AMENDMENT TO THE SEQUENCE LISTING

Please replace the Sequence listing submitted originally with the application with the amended Sequence listing submitted herewith.

REMARKS

Status of the Claims

Claims 26, 30 and 31 are pending in the application. Claims 26, 30 and 31 stand rejected. Claims 26 and 31 are amended herein.

Claim amendments

Claim 26 is amended to overcome the 35 U.S.C 112, first paragraph and second paragraph rejections. The term " has" in claim 26 is replaced with the term "consisting of". The amended claim now recites a method of producing activated T cells directed towards stratum corneum chymotrytic enzyme(SCCE). This method comprises the steps of: exposing the exposing dendritic cells to a SCCE polypeptide consisting of an amino acid sequence selected from the group consisting of SEQ ID Nos. 31, 32, 33, 34, 35, 36, 80, 86, 99 and amino acid sequence encoded by the DNA of SEQ ID No. 30, thereby producing activated dendritic cells, and exposing the activated dendritic cells to T cells, where the activated dendritic cells would present the SCCE polypeptide to the T cells, thereby producing activated T cells directed towards the SCCE polypeptide.

Additionally, claim 31 is amended to overcome the 35 U.S.C. 112, first paragraph rejection. Amended claim 31 is now directed to the use of the method

discussed *supra* in an individual who has, is suspected of having or is at risk of getting ovarian or prostate cancer.

Amended Sequence Listing

Applicant enclose a paper copy of the sequence listing, a computer readable form and a sequence compliance statement. The SEQ ID No. 30 provided with originally filed Sequence listing was incorrect. Applicant submits, however, that the cDNA sequence of SCCE was known in the art. A person having ordinary skill in this art would readily recognize that the originally provided SEQ ID No. 30 was erroneous and use the correct SCCE sequence to practice the method recited in the Applicant's claim. Accordingly, no new matter has been added to the specification by Applicant's correction of the Sequence Listing.

The 35 U.S.C. §112, First Paragraph, Rejection

Claims 26 and 30-31 are rejected under 35 U.S.C. 112, first paragraph for not complying with the written description requirement and for not enabling any person skilled in the art to which it pertains or with which it is most clearly connected to make and use the invention commensurate in scope with the claims. Applicant respectfully traverses this rejection.

The Examiner states that the claims recite the term "has" which is open claim language and encompasses peptides in addition to the ones recited in

the claim. Hence, the Examiner maintains that the specification does not reasonably provide a written description for a method of producing activated T cells directed towards any stratum corneum chymotrytic enzyme comprising the step of exposing dendritic cells to any strateum corneum chymotrytic enzyme or any fragment thereof. Additionally, the rejection of the claims were also maintained since there was lack of evidence in the specification regarding the usefulness of this method in any cancer other than ovarian cancer as disclosed by the specification and prostate cancer as taught by the prior art.

Applicant submits that claim 26 has been amended as discussed *supra*. The amended claim 26 is now directed to specific 9-mer peptides that are disclosed in the specification and to the polypeptide encoded by the SCCE cDNA known in the art. Hence, the amended claim 26 complies with the written description requirement and also enables a person skilled in the art to make and use the invention as claimed. Additionally, the Applicant has also amended claim 31 to limit the method to ovarian or prostate cancer.

Furthermore, these claims are rejected under new grounds since the specification of the instant invention does not describe the SCCE proteins that are encoded by SEQ ID No. 30. Applicant respectfully traverses this rejection.

The Examiner states that since the SEQ ID No. 30 disclosed in the instant invention does not match with the cDNA sequence of SCCE disclosed by **Hannson** *et al.*, the nature of the polypeptide encoded by SEQ ID No. 30 is not clear. As discussed *supra*, Applicant submits that the polypeptide encoded by the amended SEQ ID No. 30 is a full-length human SCCE polypeptide. Based on the

above-mentioned amendments and remarks, Applicant respectfully requests the withdrawal of rejection of claims 26, 30 and 31 under 35 U.S.C. 112, first paragraph.

The 35 U.S.C. §112, Second Paragraph, Rejection

Claims 26 and 30-31 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses this rejection.

For the same reasons with regards to SEQ ID No. 30 as discussed *supra*, the Examiner states that it is not clear whether the polypeptide encoded by SEQ ID No. 30 is a full-length polypeptide, a mature SCCE polypeptide or the SCCE polypeptide lacking the signal sequence.

As discussed *supra*, Applicant submits that the polypeptide encoded by the amended SEQ ID No. 30 is a full-length human polypeptide. Based on the above-mentioned amendments and remarks, Applicant respectfully requests the withdrawal of rejection of claims 26, 30 and 31 under 35 U.S.C. 112, second paragraph.

The 35 U.S.C. §103 Rejection

Claims 26, 30-31 are still rejected under 35 U.S.C. §103(a) as being unpatentable over **Paglia** *et al.* in view of **Cohen** *et al.* Applicant respectfully traverses this rejection.

The Examiner states that due to open language in claim 26 as well as its indefinite nature as discussed *supra*, the claim encompasses additional peptides and reads on the mature SSCE polypeptide of 224 amino acids taught by **Cohen** *et al.* Therefore, the Examiner maintains that in view of the combined teachings of **Paglia** *et al.* and **Cohen** *et al.*, the instant invention as a whole would be obvious to one of skill in the art.

The amended claim 26 is directed to the use of SCCE peptides that are 9 amino acids in length and to a full length human SCCE polypeptide that is 253 amino acids long. In distinct contrast, **Paglia** *et al.* teach that dendritic cells that were exposed to a soluble antigen *in vitro* were able to prime *in vivo* antigen-specific cytotoxic T lymphocytes. **Cohen** *et al.* compare the sequence of PS133 polypeptide with the sequence of a serine protease such as SCCE (SEQ ID No. 33) that is 224 amino acids long. **Cohen** *et al.* do not teach of 9-amino acid long SCCE peptides or a full length SCCE polypeptide of the instant invention. Furthermore, **Paglia** *et al* and **Cohen** *et al* combined neither teach nor suggest the use of the peptides of the instant invention to activate T cells as is taught by the instant invention. Indeed, the combination of these two prior art references do not motivate a person having ordinary skill in this art to arrive at the claimed invention with any reasonable expectation of success.

Applicants assert that obviousness requires that the prior art relied upon fairly teach or suggest all the elements of the instant invention and that an incentive or motivation be present in the prior art references to produce the claimed invention with reasonable expectation of success in its production. The Applicants have shown that **Paglia** *et al.* and **Cohen** *et al.* do not teach or suggest all the elements of the instant invention, nor do they provide an incentive or motivation to produce the claimed invention with any reasonable expectation of success in its production. Hence, the subject matter of the instant invention is not obvious to one with ordinary skill in the art at the time the invention was made. Accordingly, based on the above-mentioned amendments and remarks, Applicant respectfully requests withdrawal of rejection of claims 26, 30-31 under 35 U.S.C. §103.

The Obviousness-Type Double Patenting, Rejection

The Examiner has maintained rejection of claims 26 and 30-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-11 of copending Application No. 10/372,521 since Applicant did not submit a terminal disclaimer to obviate this rejection. Applicant respectfully traverses this rejection.

Applicant submits the terminal disclaimer along with this response. Accordingly, Applicant respectfully requests the withdrawal of rejection of claims 26 and 30-31 under the doctrine of obviousness-type double patenting.

This is intended to be a complete response to the Final Office Action mailed November 12, 2004. Applicant submit that the pending claims are in condition for allowance. If any issues remain outstanding, please telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: 5/11/05

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